

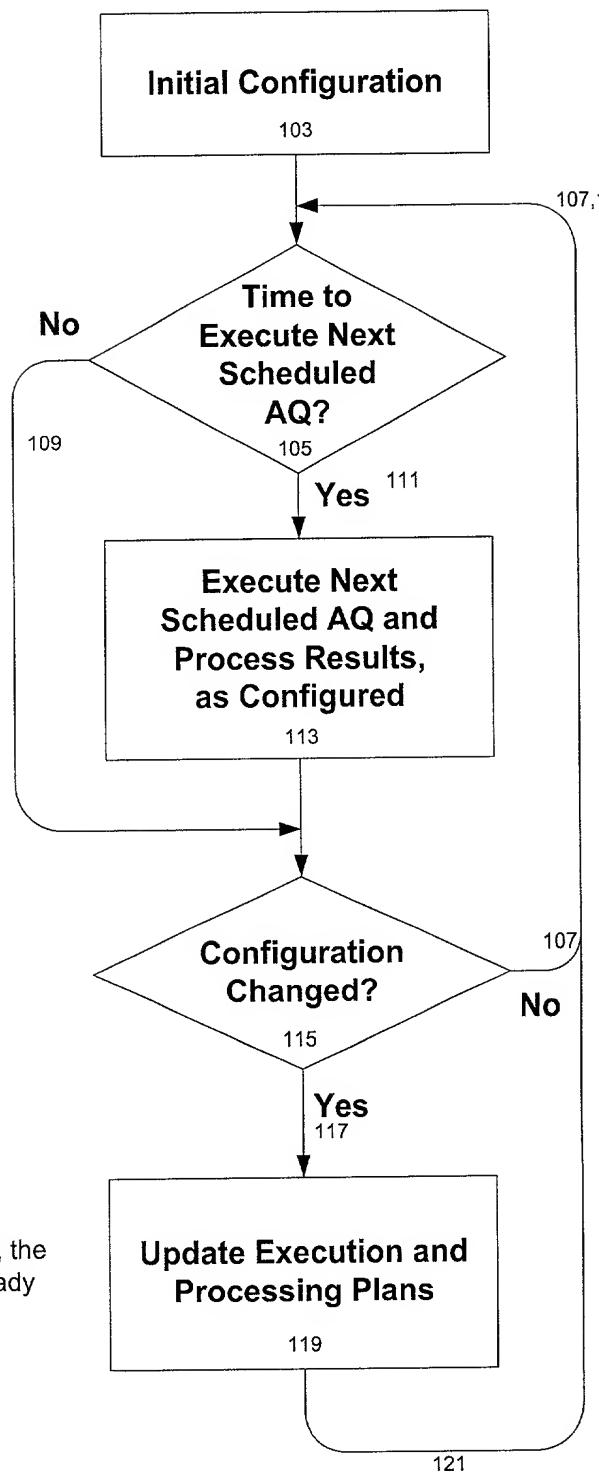
103: The **Initial Configuration** is used to define the execution and processing plans, including the following:

- **Query (search / trigger criteria)**
- **Admin Scope**
- **Admin Schedule**
- **Admin Activity**
- **Admin Query**

TO GO ON

143: In this step the next scheduled **Admin Query**, is executed, querying the database, searching for records meeting the given **Admin Query** conditions, and processing all PRs in the **Result Set**.

119: Upon detection of changes in the execution and, or the processing plans, the system adopts the new plans and is ready to continue with the next cycle

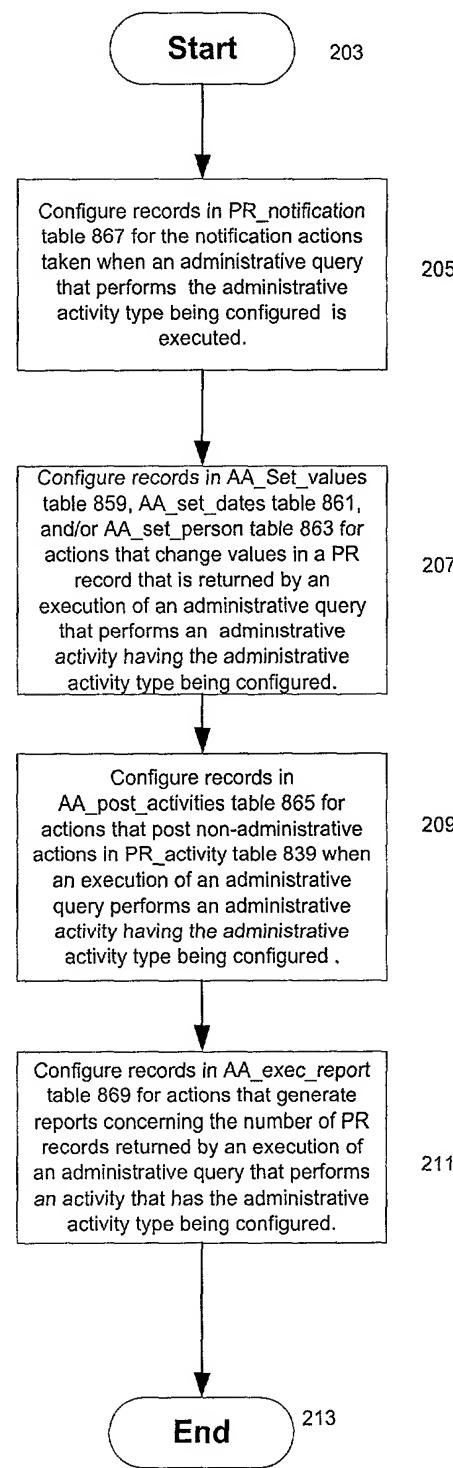


105: In this step the next Admin Query, if any, is executed, querying the database, searching for records meeting the given **Admin Query** conditions.

115: A periodical check for whether the current execution plan and process plan have changed, e.g.,

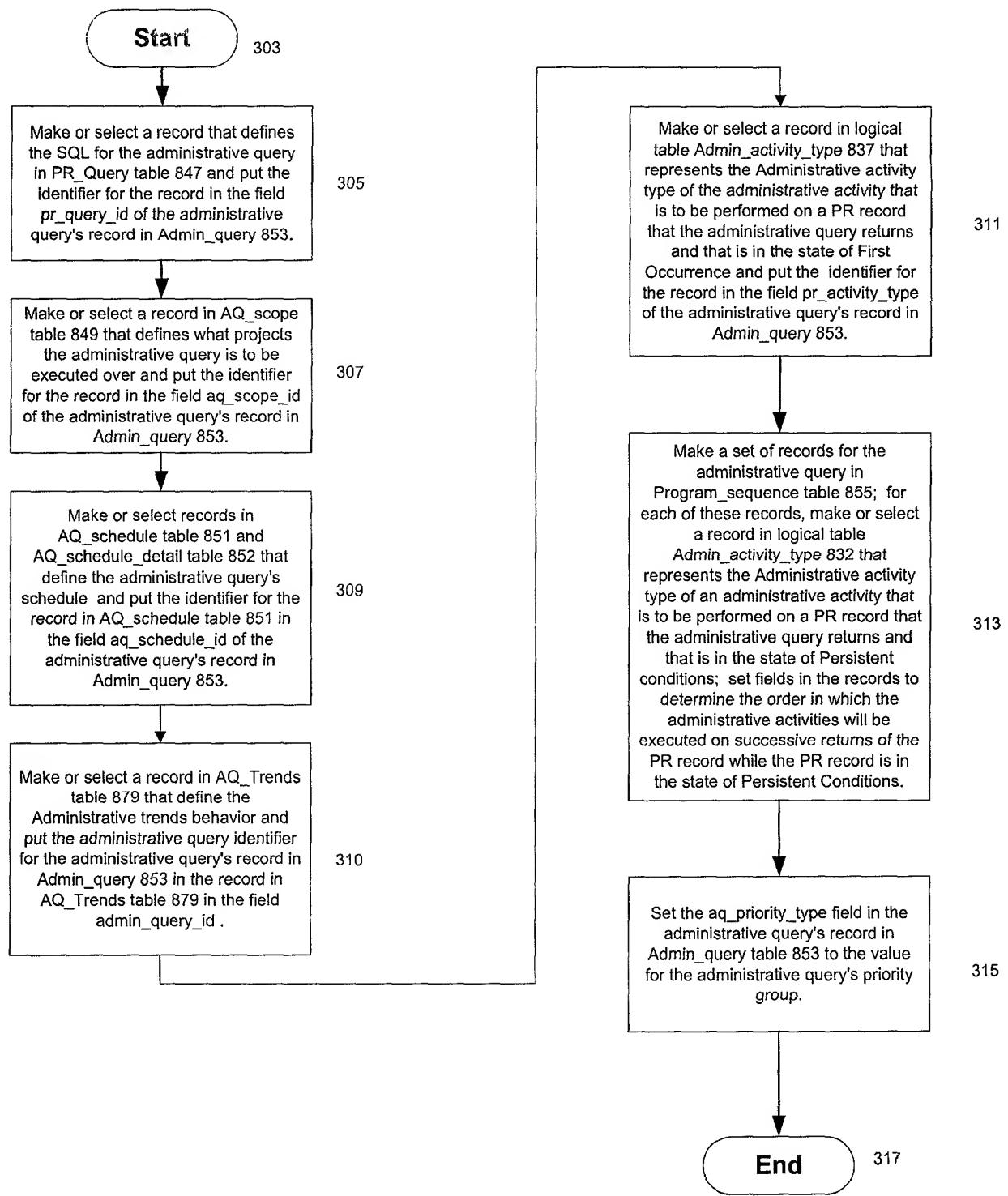
- Removal of exiting AQs.
- Changes in Admin Schedule.
- Changes in Admin Scope (adding or removing Projects, i.e., work areas).
- New Admin Activities.
- New Notification Rules.

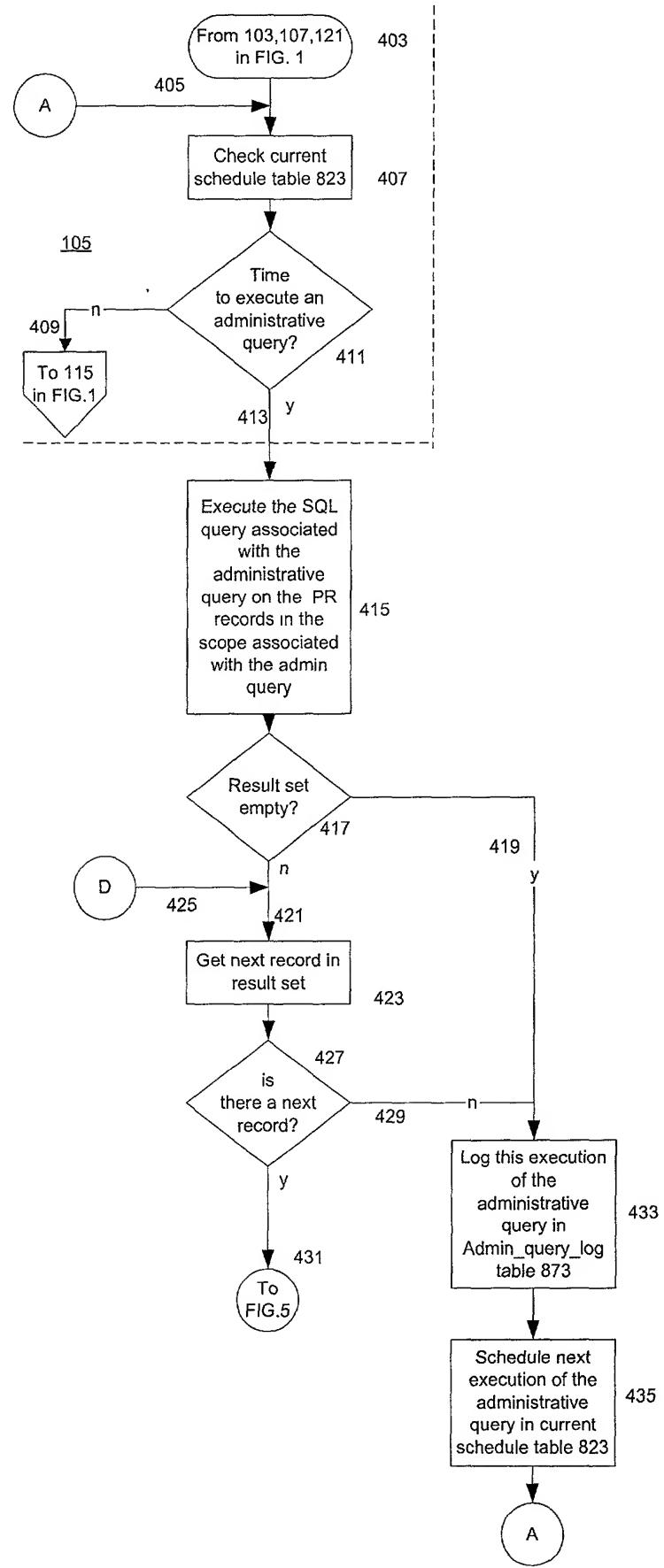
FIG. 1

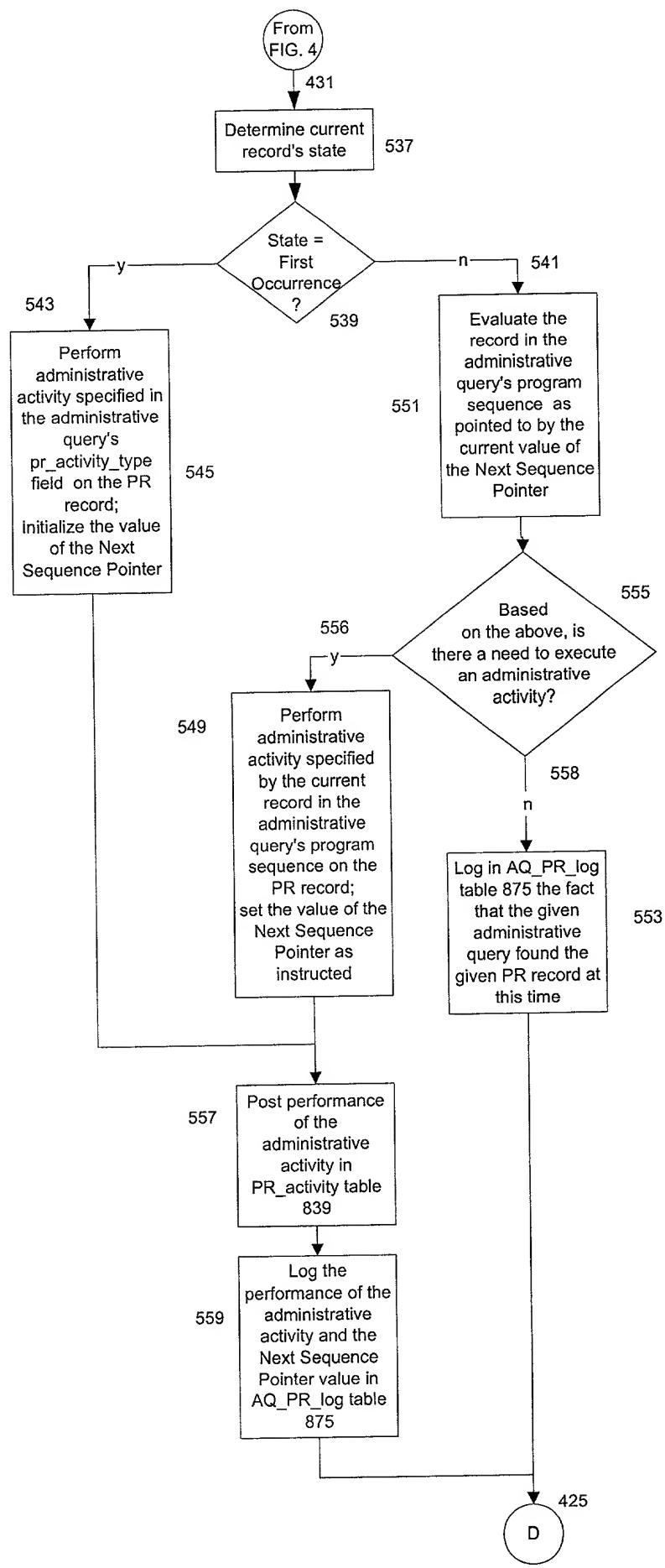


201

FIG. 2







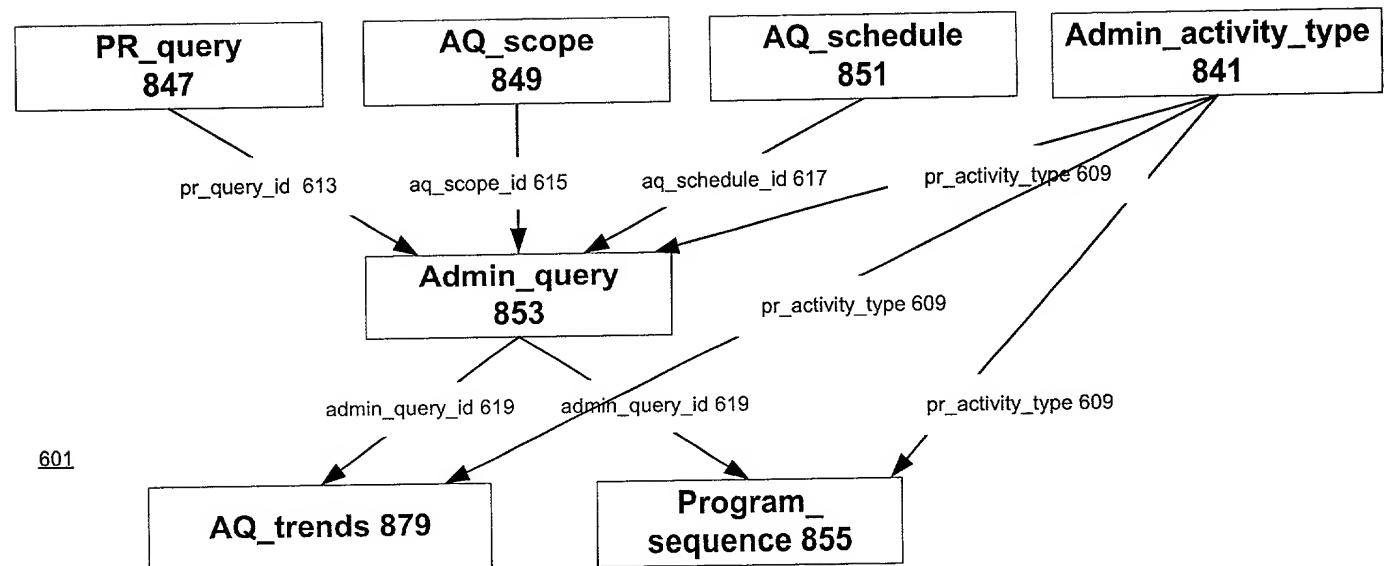
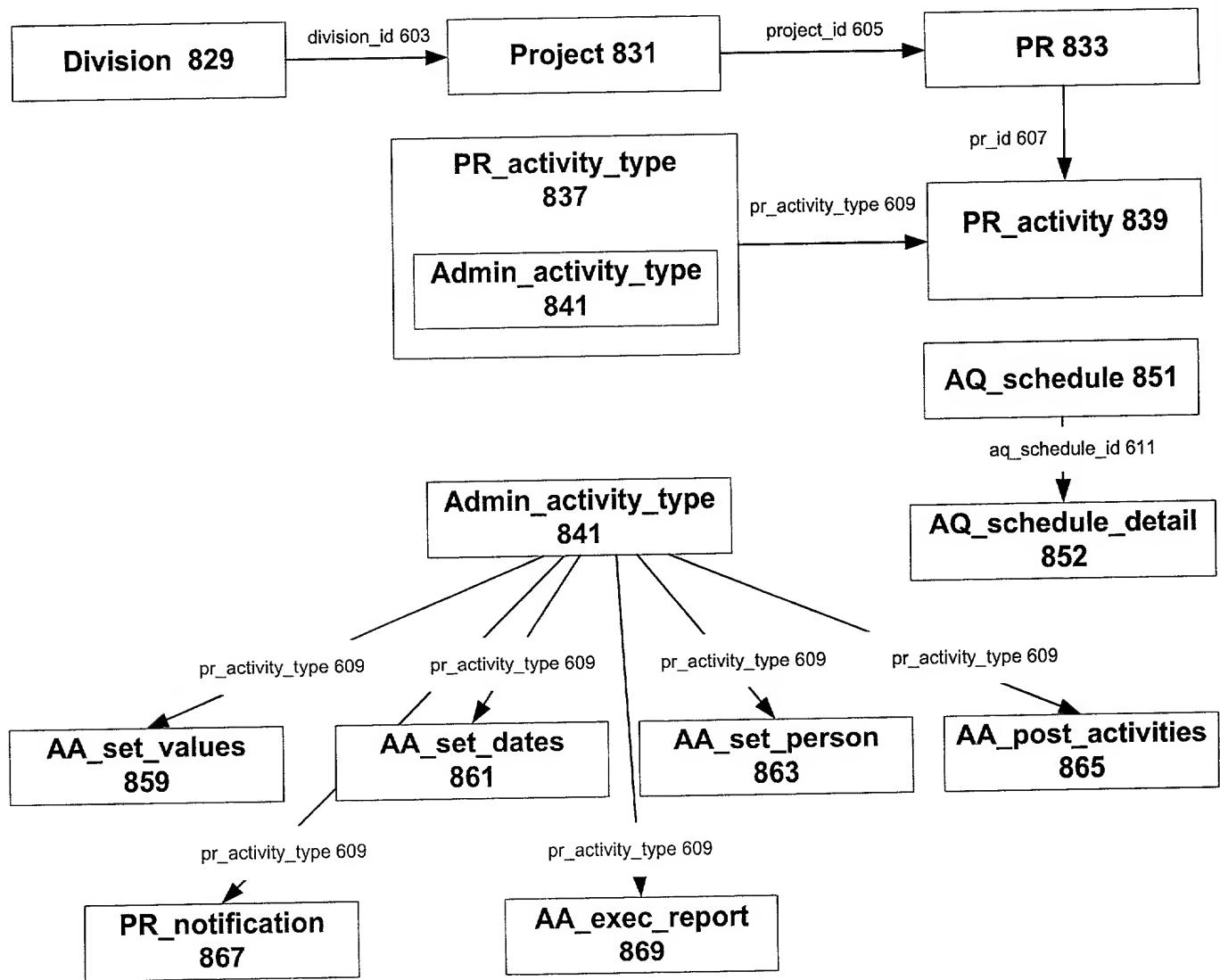
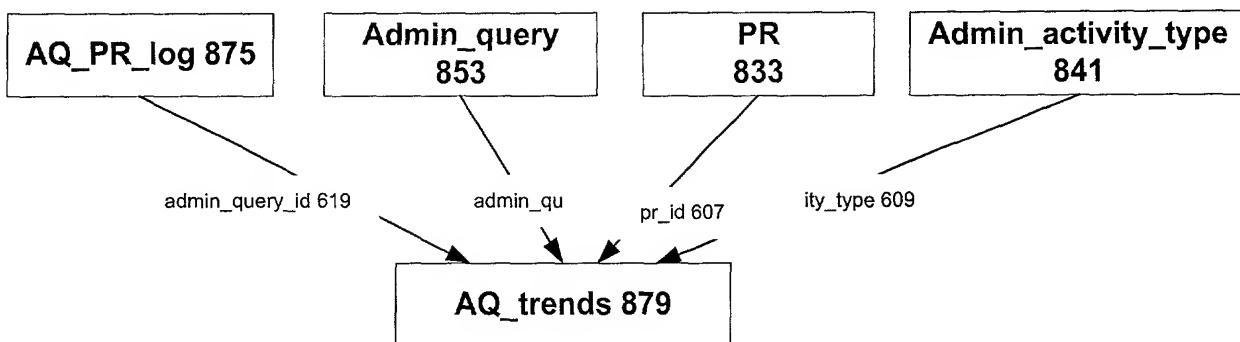
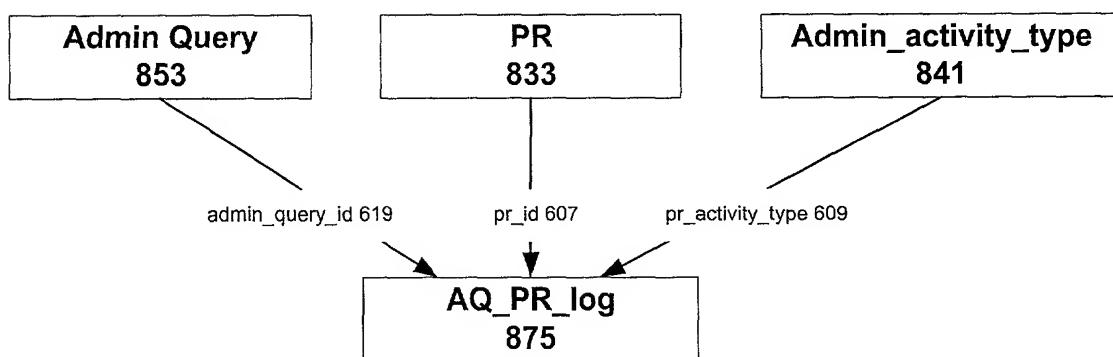
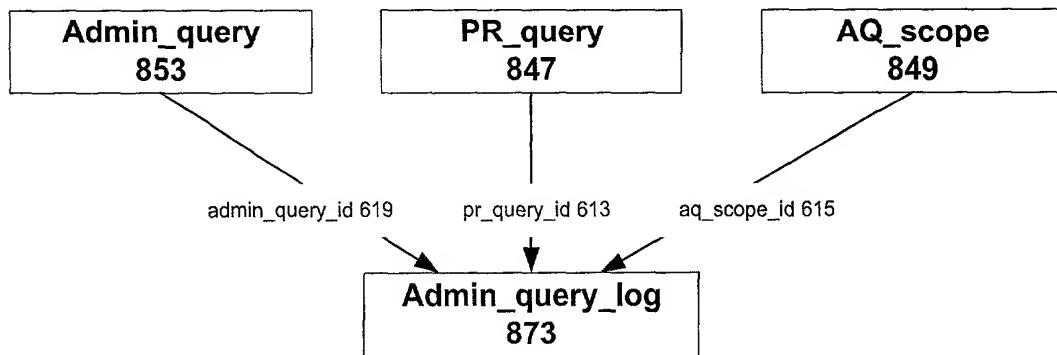


FIG. 6



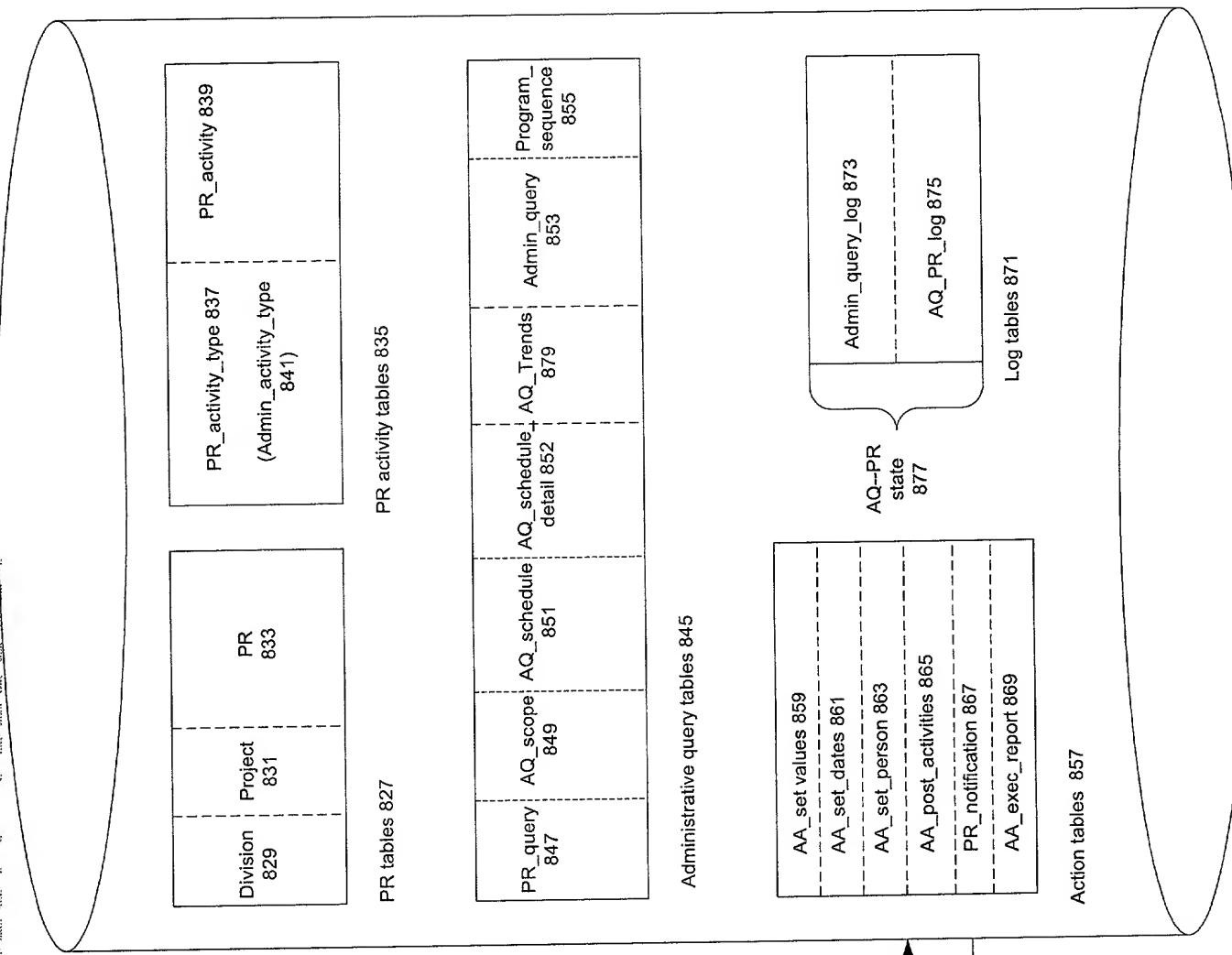
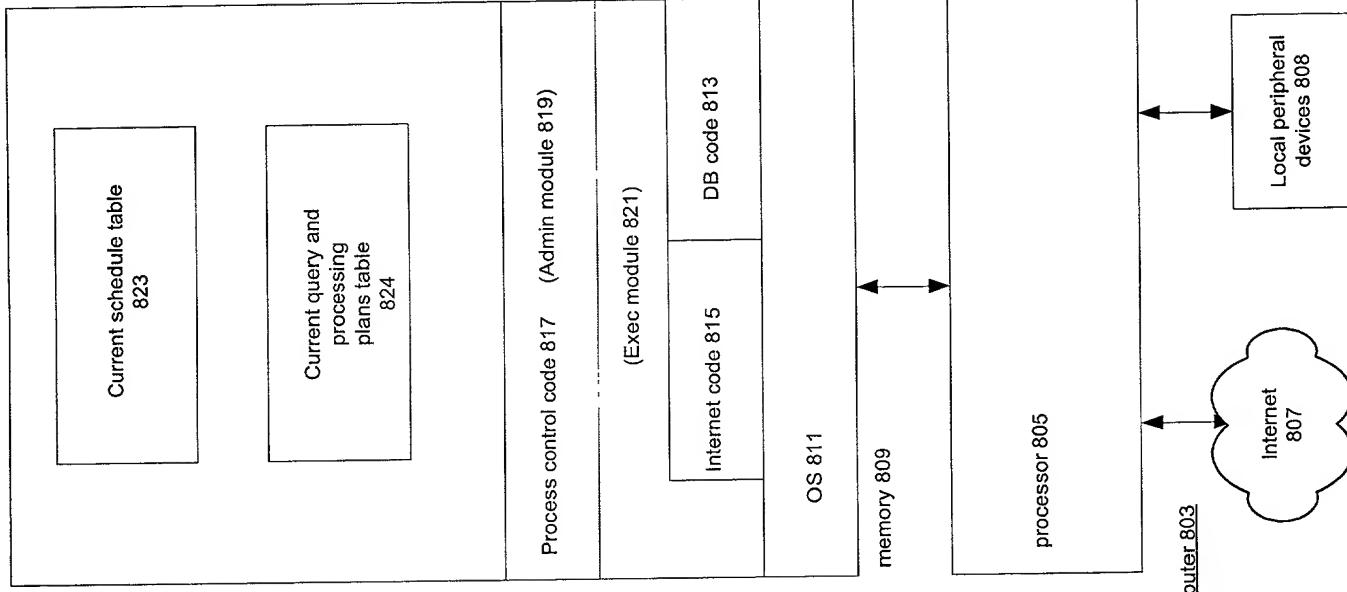


FIG. 8

DB system 825

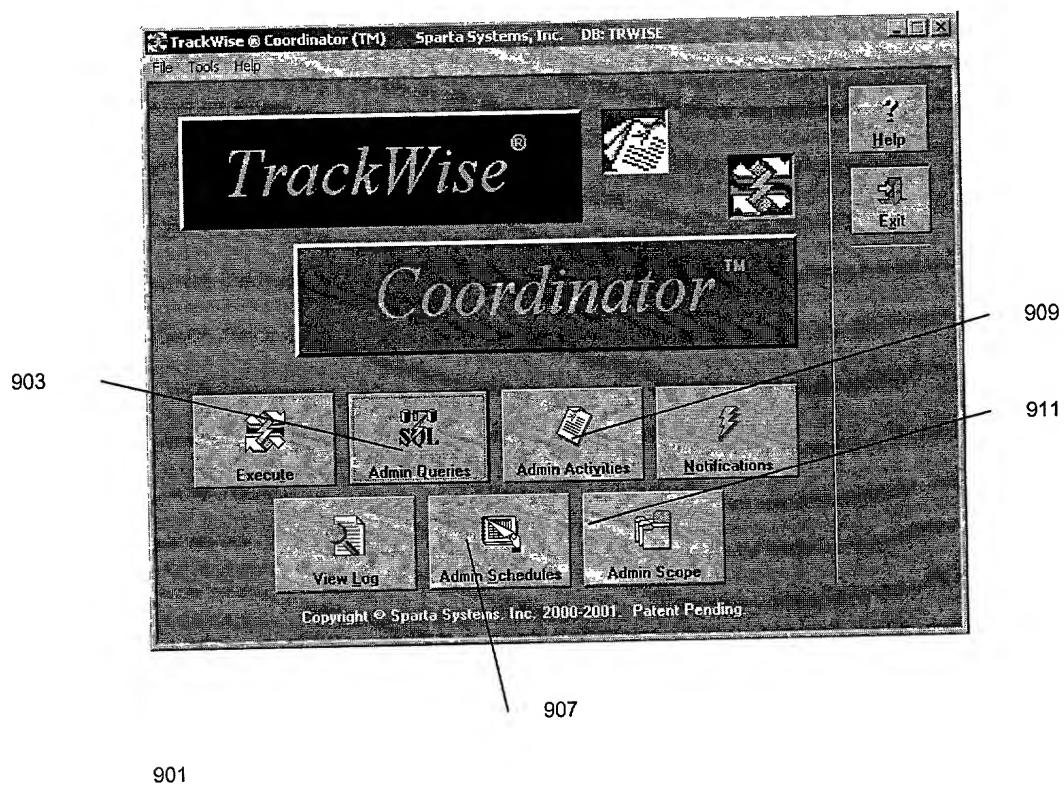
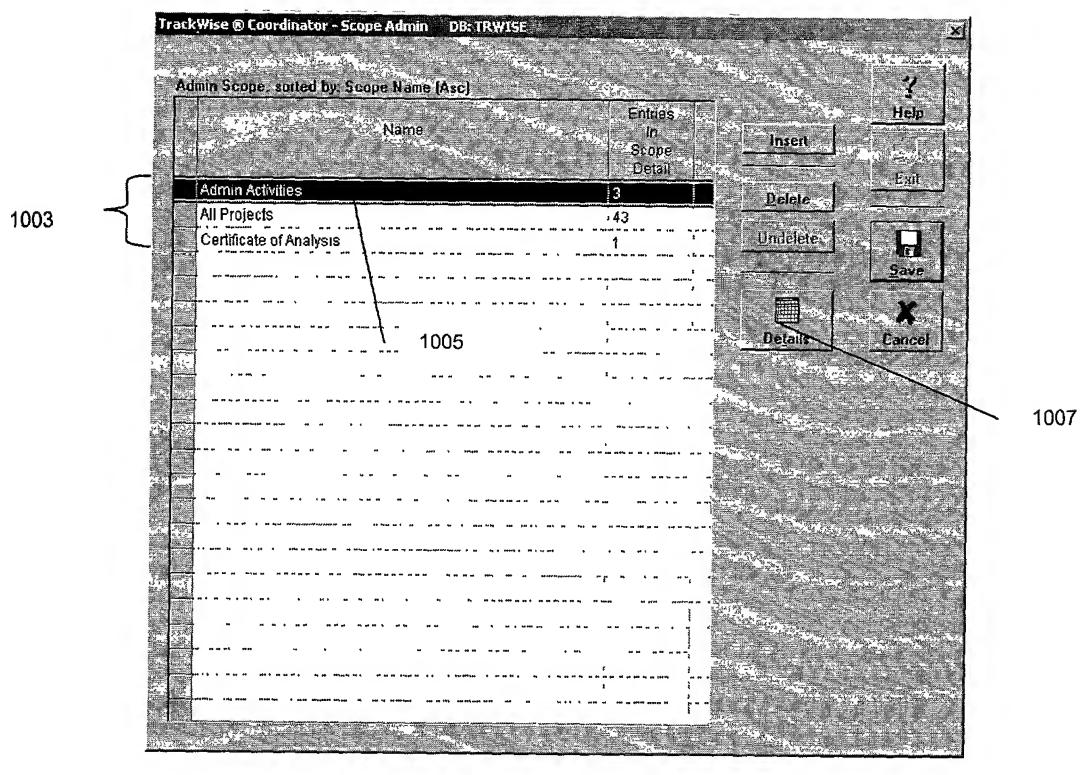


FIG. 9



1001

TrackWise ® - Admin Scope Details DB: TRWISE

Admin Scope: Admin Activities

Scope: sorted by: Included in Scope (Desc)

Department	Record Type	Included in Scope
CAPA - New Jersey	Action Item	<input checked="" type="checkbox"/>
CAPA - California	Action Item	<input checked="" type="checkbox"/>
CAPA - Ireland	Action Item	<input checked="" type="checkbox"/>
Audits - Ireland	Observation	<input type="checkbox"/>
Audits - California	Audit	<input type="checkbox"/>
Audits - New Jersey	Observation	<input type="checkbox"/>
Audits - California	Observation	<input type="checkbox"/>
CAPA - California	Corrective Action	<input type="checkbox"/>
CAPA - California	Preventive Action	<input type="checkbox"/>
Audits - New Jersey	Audit	<input type="checkbox"/>
CAPA - Ireland	Corrective Action	<input type="checkbox"/>
CAPA - Ireland	Preventive Action	<input type="checkbox"/>
Audits - Ireland	Audit	<input type="checkbox"/>
CAPA - New Jersey	Corrective Action	<input type="checkbox"/>
CAPA - New Jersey	Preventive Action	<input type="checkbox"/>
Change Control - California	Request	<input type="checkbox"/>
Change Control - Ireland	Request	<input type="checkbox"/>
Change Control - New Jersey	Request	<input type="checkbox"/>
Complaints - California	Complaint	<input type="checkbox"/>
Complaints - California	Inquiry	<input type="checkbox"/>
Complaints - Ireland	Complaint	<input type="checkbox"/>
Complaints - Ireland	Inquiry	<input type="checkbox"/>

Buttons: Help, OK, Cancel

1009

1013

FIG. 10

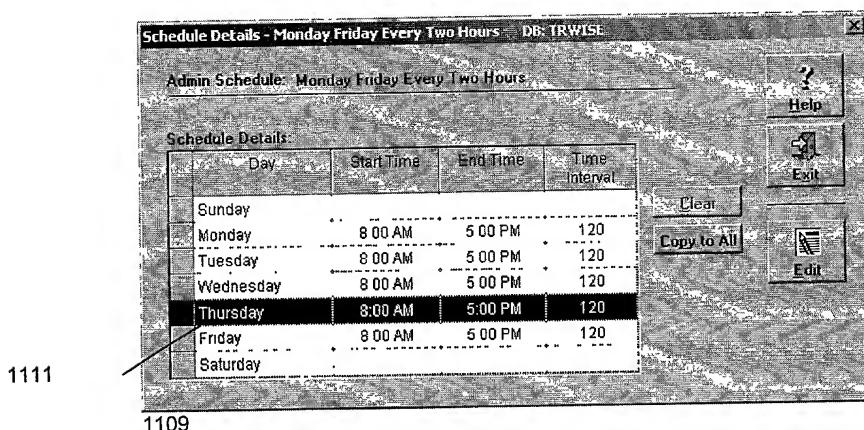
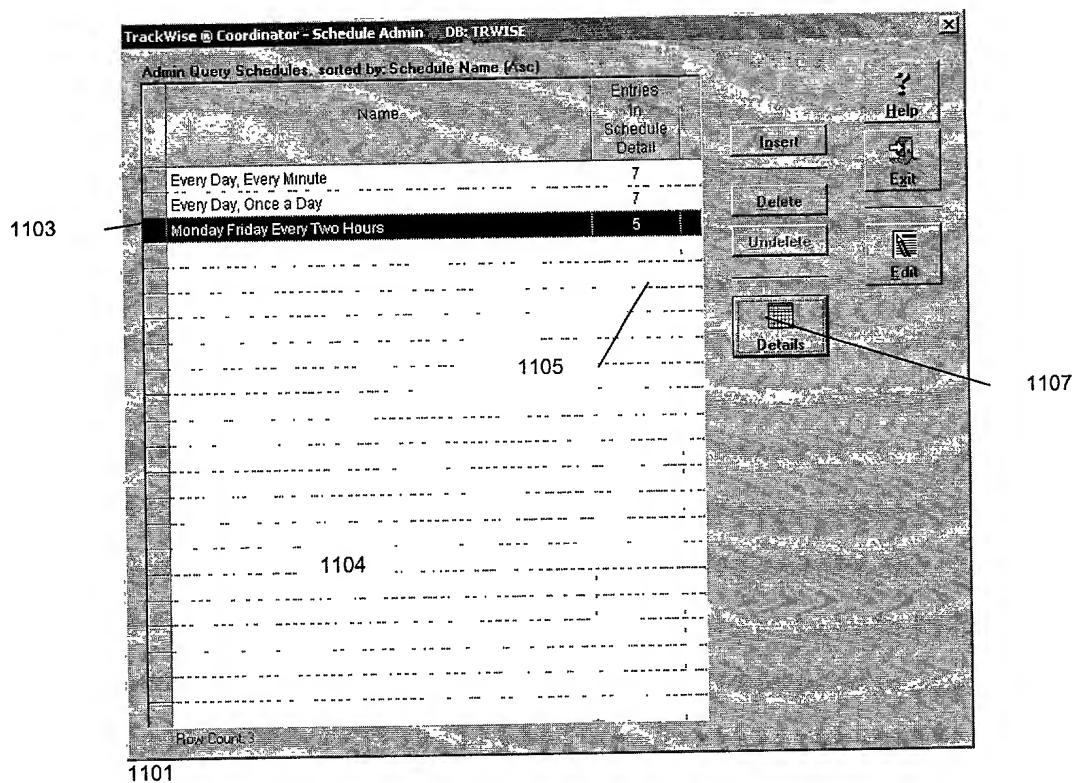


FIG. 11

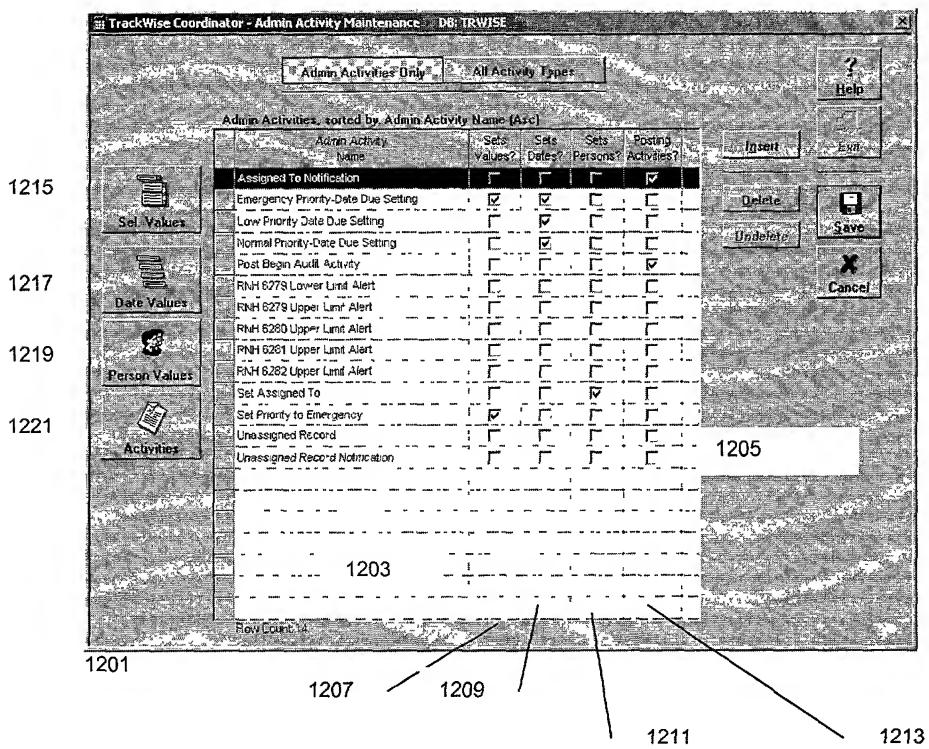


FIG. 12

Administration of Setting Selection Values

Admin Activity: Set Priority to Emergency

Set values, sorted by Field Name (Asc)

Field Name to Set	Field Type	Operator	Set Values
Additional Samples Tested?	Selection		
Affected SOP	Selection		
Assessment Method	Selection		
Assignable Cause	Multi-Selection		
Condition	Selection		
Disposition of Samples	Selection		
Final Disposition	Selection		
Governing SOP	Selection		
Impact	Selection		
Location	Selection		
Mfg Stage	Selection		
Phase	Selection		
Priority	Selection	Set	Emergency
Product Family	Selection		
Product(s)	Multi-Selection		
Proposed Disposition	Selection		
Type	Selection		

1302 1303 1305 1307 1309

1301 1306

Mfg Stage	Selection		
Phase	Selection		
Priority	Selection	Set	Emergency
Product Family	Selection	Increment	
Product(s)	Multi-Selection	Set	1311
Proposed Disposition	Selection	Clear	
Type	Selection		

1310

Selection Values DB: TRWISE

Emergency
Low
Normal

1313

FIG 13

1402

Administration of Setting Date Values

Admin Activity Assigned To Notification:

Field to Set	If Field Is Blank, Base Field to Use	Add Value	Time Units	If Field Already Set, Base Field to Use	Add Value	Time Units	Business Days Rule
Analyst Approval On							
Audit Start Date							
Closed On							
Date Due							
Date Occurred							
Director Approval On							
Discovery Date							
Next Audit Date							
QA Approval On							
Received Questionnaire							
Response Due Date							
Sent Questionnaire							
Supervisor Approved On							

1403 1405 1411 1412

1401 1407 1409 1413

Save Cancel

1415

Administration of Setting Date Values

Admin Activity Assigned To Notification:

Field to Set	If Field Is Blank, Base Field to Use	Add Value	Time Units	If Field Already Set, Base Field to Use	Add Value	Time Units	Business Days Rule
Analyst Approval On							
<input checked="" type="checkbox"/> Audit Start Date	Date Created						
Closed On	Date Created						
Date Due	Date Due						
Date Occurred	Date Occurred						
Director Approval On	Director Approval On						
Discovery Date	Discovery Date						
Next Audit Date	Next Audit Date						
QA Approval On	QA Approval On						
Received Questionnaire	Received Questionnaire						
	Response Due Date						

1414 1417

1421

1419

Administration of Setting Date Values

Closed On			
<input checked="" type="checkbox"/> Date Due	Date Created	30	Day(s)
Date Occurred			

1418

1424

Administration of Setting Date Values

Closed On			
<input checked="" type="checkbox"/> Date Due	Date Created	30	Day(s)
Date Occurred			
Director Approval On			
Discovery Date			
Next Audit Date			

1422

1423

1425

Calendar

Minute(s)
Hour(s)
Day(s)
Week(s)

FIG. 14

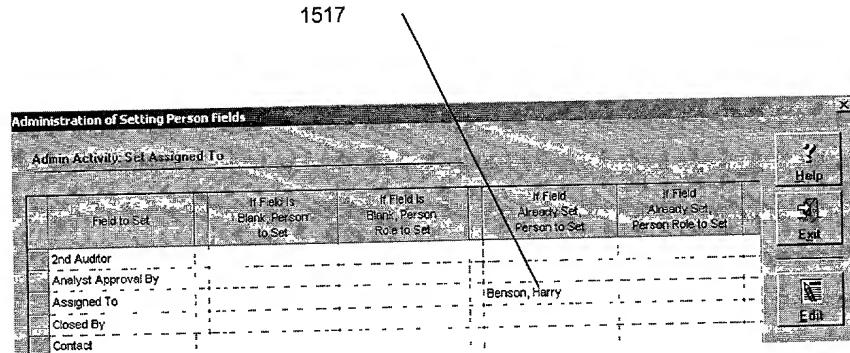
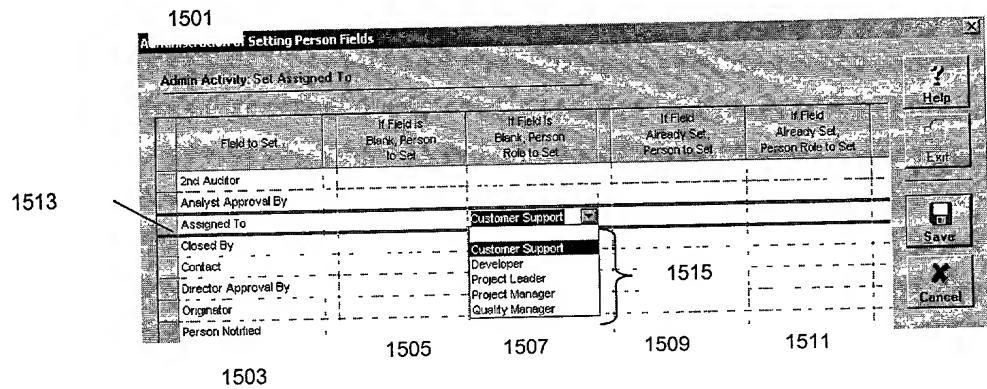


FIG. 15

1602

Administration of Posting Activities

Admin Activity: Post Begin Audit Activity

Activity to Post	Posting Mode	Date Reference Field	Value	Time Units	Business Days Rule	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
Begin Audit	Perform						
Begin Change Control	Schedule						
Begin Investigation	Perform						
*Change Control Cancelled							
Change Request							
Close							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment			1603				
Complete Correspondence			1605				
			1607				
			1609				
			1611				

Note: Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only.

1601

1604

1607

1613

Administration of Posting Activities

Admin Activity: Post Begin Audit Activity

Activity to Post	Posting Mode	Date Reference Field	Value	Time Units	Business Days Rule	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
Begin Audit	Schedule	Current Date/Time	2	Day(s)	Calendar	Contact	
Begin Change Control							
Begin Investigation							
*Change Control Cancelled			1614				
Change Request			1615				
Close							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment							
Complete Correspondence							

Note: Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only.

FIG. 16

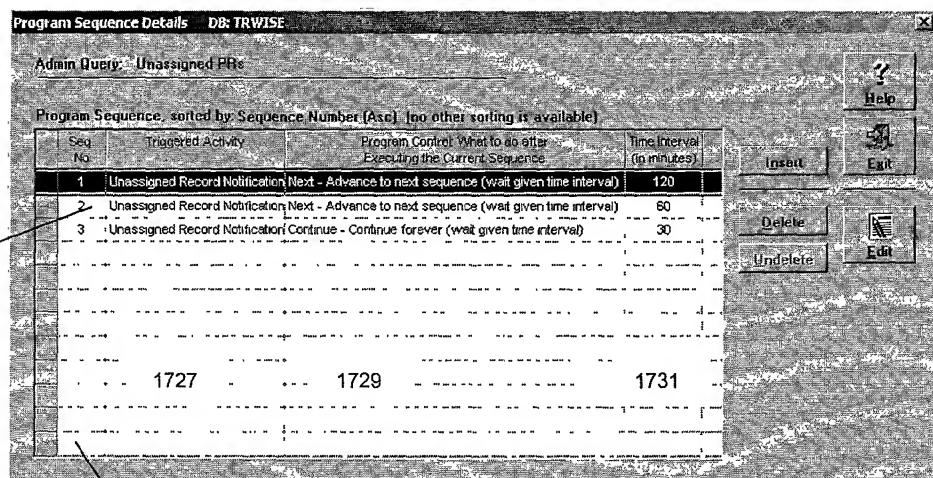
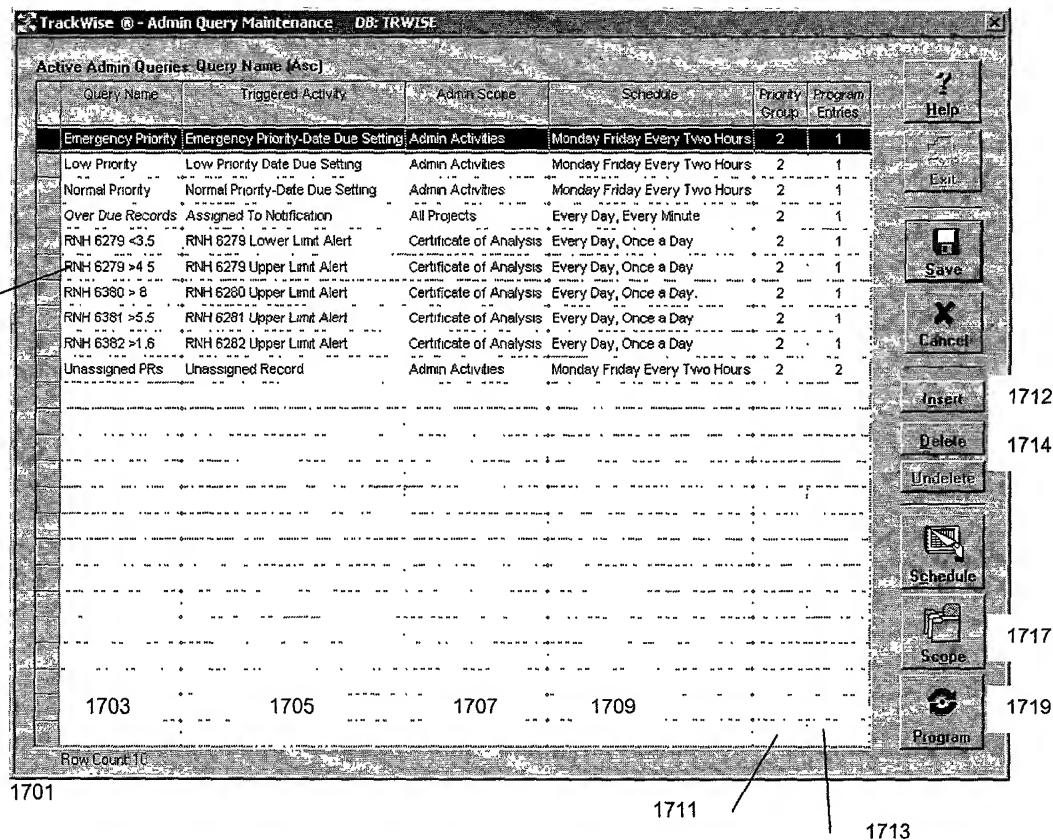


FIG. 17